

1029WOORD01

| 0     | For receiving Office use only   |   |  |
|-------|---|---|--|
| 0-1   | International Application No.   |   |  |
| 0-2   | International Filing Date   |   |  |
| 0-3   | Name of receiving Office and "PCT International Application"  |   |  |
|       |   |   |  |
| 0-4   | Form - PCT/RO/101 PCT Request   |   |  |
| 0-4-1 | Prepared using  | PCT-EASY Version 2.92                                       |  |
|       |   | (updated 01.01.2003)  |  |
| 0-5   | Petition  |   |  |
|       | The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty |   |  |
| 0-6   | Receiving Office (specified by the applicant)   | European Patent Office (EPO) (RO/EP)                        |  |
| 0-7   | Applicant's or agent's file reference   | 1029WOORD01   |  |
| 1     | Title of invention  | DOSAGE FORM CONTAINING PDE 4 INHIBITOR AS ACTIVE INGREDIENT |  |
| II    | Applicant   |   |  |
| H-1   | This person is:   | applicant only  |  |
| 11-2  | Applicant for   | all designated States except US                             |  |
| 11-4  | Name  | ALTANA PHARMA AG  |  |
| 11-5  | Address:  | Byk-Gulden-Str. 2<br>D-78467 Konstanz<br>Germany            |  |
| 11-6  | State of nationality  | DE  |  |
| 11-7  | State of residence  | DE  |  |
| 11-8  | Telephone No.   | +49-(0)7531-845338  |  |
| il-9  | Facsimile No.   | +49-(0)7531-845321  |  |
|       | e-mail  | DEKON.IPPA-DE@altanapharma.com                              |  |

| III-1               | Applicant and/or inventor |   |
|---------------------|---------------------------|---|
| 111-1-1             | This person is:           | applicant and inventor  |
| [  -1-2             | Applicant for             | US only   |
| III-1-3             | Inventor for              | EA: (AM AZ BY KG KZ MD RU TJ TM); EP: (AT BE BG CH&LI CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT SE SI SK TR); AE AL AU BA BR CA CN CO CU DZ EC GE HR ID IL IN IS JP KR LT LV MA MK MX NO NZ PH PL RO SG TN UA US VN YU ZA ZW |
| III-1 <del>-4</del> | Name (LAST, First)        | DIETRICH, Rango   |
| III-1-5             | Address:                  | Im Tiergarten 16<br>D-78465 Konstanz<br>Germany   |
| 111-1-6             | State of nationality      | DE  |
| 111-1-7             | State of residence        | DE  |
| 111-2               | Applicant and/or inventor |   |
| 111-2-1             | This person is:           | applicant and inventor  |
| 111-2-2             | Applicant for             | US only   |
| III-2-3             | Inventor for              | EA: (AM AZ BY KG KZ MD RU TJ TM); EP: (AT BE BG CH&LI CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT SE SI SK TR); AE AL AU BA BR CA CN CO CU DZ EC GE HR ID IL IN IS JP KR LT LV MA MK MX NO NZ PH PL RO SG TN UA US VN YU ZA ZW |
| 111-2-4             | Name (LAST, First)        | EISTETTER, Klaus  |
| III-2-5             | Address:                  | Säntisblick 7<br>D-78465 Konstanz<br>Germany  |
| 111-2-6             | State of nationality      | DE  |
| 111-2-7             | State of residence        | DE  |

| 111-3            | Applicant and/or inventor   |  |
|------------------|---|--|
| III-3-1          | This person is:   | applicant and inventor   |
| 111-3-2          | Applicant for   | US only  |
| 111-3-3          | Inventor for  | EA: (AM AZ BY KG KZ MD RU TJ TM); EP:                                      |
|                  |   | (AT BE BG CH&LI CY CZ DE DK EE ES FI FR                                    |
|                  |   | GB GR HU IE IT LU MC NL PT SE SI SK TR);                                   |
|                  |   | AE AL AU BA BR CA CN CO CU DZ EC GE HR                                     |
|                  |   | ID IL IN IS JP KR LT LV MA MK MX NO NZ                                     |
|                  |   | PH PL RO SG TN UA US VN YU ZA ZW   |
| 111-3-4          | Name (LAST, First)  | NEY, Hartmut   |
| 111-3-5          | Address:  | Peter-Thumb-Str. 46  |
|                  |   | D-78464 Konstanz   |
|                  |   | Germany  |
| III-3-6          | State of nationality  | DE   |
| III-3 <b>-</b> 7 | State of residence  | DE   |
| IV-1             | Agent or common representative; or  |  |
|                  | address for correspondence The person identified below is                     | common representative  |
|                  | hereby/has been appointed to act on   | Common rope openica of Ac  |
|                  | behalf of the applicant(s) before the competent International Authorities as: |  |
| IV-1-1           | Name  | ALTANA PHARMA AG   |
| IV-1-2           | Address:  | Byk-Gulden-Straße 2  |
|                  |   | D-78467 Konstanz   |
|                  |   | Germany  |
| IV-1-3           | Telephone No.   | +49-(0)7531-845338   |
| IV-1-4           | Facsimile No.   | +49-(0)7531-845321   |
| IV-1-5           | e-mail  | DEKON.IPPA-DE@altanapharma.com   |
| V                | Designation of States   |  |
| V-1              | Regional Patent (other kinds of protection or treatment,                      | EA: AM AZ BY KG KZ MD RU TJ TM and any                                     |
|                  | if any, are specified between   | other State which is a Contracting State                                   |
|                  | parentheses after the designation(s) concerned)                               | of the Eurasian Patent Convention and of                                   |
|                  | 55.155.1155,  | the PCT  |
|                  |   | EP: AT BE BG CH&LI CY CZ DE DK EE ES FI                                    |
|                  |   | FR GB GR HU IE IT LU MC NL PT SE SI SK                                     |
|                  |   | TR and any other State which is a  |
|                  |   | Contracting State of the European Patent                                   |
| V-2              | National Patent   | Convention and of the PCT  |
| V - 2.           | (other kinds of protection or treatment,                                      | AE AL AU BA BR CA CN CO CU DZ EC GE HR                                     |
|                  | If any, are specified between parentheses after the designation(s)            | ID IL IN IS JP KR LT LV MA MK MX NO NZ<br>PH PL RO SG TN UA US VN YU ZA ZW |
|                  |   |  |

| V-5     | Precautionary Designation Statement   |                                       |
|---------|---|---------------------------------------|
|         | In addition to the designations made  |                                       |
|         | under items V-1, V-2 and V-3, the   |                                       |
|         | applicant also makes under Rule 4.9(b)  |                                       |
|         | all designations which would be permitted under the PCT except any              |                                       |
|         | designation(s) of the State(s) Indicated  |                                       |
|         | under item V-6 below. The applicant   |                                       |
|         | declares that those additional  |                                       |
|         | designations are subject to confirmation  |                                       |
|         | and that any designation which is not confirmed before the expiration of 15     |                                       |
|         | months from the priority date is to be  |                                       |
|         | regarded as withdrawn by the applicant  |                                       |
|         | at the expiration of that time limit.   |                                       |
| V-6     | Exclusion(s) from precautionary designations                                    | NONE                                  |
| Vi-1    | Priority claim of earlier regional  |                                       |
| 1044    | application   |                                       |
| VI-1-1  | Filing date   | 20 February 2002 (20.02.2002)         |
| VI-1-2  | Number  | 02003811.3                            |
| VI-1-3  | Regional Office   | EP                                    |
| VI-2    | Priority claim of earlier national application                                  |                                       |
| VI-2-1  | Filing date   | 20 February 2002 (20.02.2002)         |
| VI-2-2  | Number  | 10207160.8                            |
| VI-2-3  | Country   | DE                                    |
| VII-1   | International Searching Authority Chosen  | European Patent Office (EPO) (ISA/EP) |
| VII-2   | Request to use results of earlier   |                                       |
|         | search; reference to that search  |                                       |
| VII-2-1 | Date  | 16 July 2002 (16.07.2002)             |
| VII-2-2 | Number  | EP02003811                            |
| VII-2-3 | Country (or regional Office)  | EP                                    |
| VIII    | Declarations  | Number of declarations                |
| VIII-1  | Declaration as to the identity of the<br>Inventor                               | -                                     |
| VIII-2  | Declaration as to the applicant's   |                                       |
|         | entitlement, as at the international filing date, to apply for and be granted a |                                       |
|         | patent  |                                       |
| VIII-3  | Declaration as to the applicant's   | 2                                     |
|         | entitlement, as at the international filing                                     |                                       |
|         | date, to claim the priority of the earlier                                      |                                       |
| VIII-4  | application   |                                       |
| VIII-4  | Declaration of inventorship (only for the purposes of the designation of the    | 1                                     |
|         | United States of America)   |                                       |
| VIII-5  | Declaration as to non-prejudicial   |                                       |
|         | disclosures or exceptions to lack of  |                                       |
|         | novelty   |                                       |

| VIII-2-1 | Declaration: Entitlement to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the International filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate: | in relation to this international application |
|----------|---|---|
|          | Name:   | ALTANA PHARMA AG                              |
|          |   | is entitled to apply for and be granted       |
|          |   | a patent by virtue of the following:          |
| VIII-2-1 |   | ALTANA PHARMA AG is entitled as employer      |
| (ii)     |   | of the inventor, DIETRICH, Rango              |
| VIII-2-1 |   | ALTANA PHARMA AG is entitled as employer      |
| (ii)     |   | of the inventor, EISTETTER, Klaus             |
| VIII-2-1 |   | ALTANA PHARMA AG is entitled as employer      |
| (ii)     |   | of the inventor, NEY, Hartmut                 |
| VIII-2-1 | This declaration is made for the  | all designations except the designation       |
| (ix)     | purposes of:  | of the United States of America               |



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| VIII-3-1           | Declaration: Entitlement to claim priority Declaration as to the applicant's entitlement, as at the International filing date, to claim the priority of the earlier application specified below, where the applicant is not the applicant who filed the earlier application or where the applicant's name has changed since the filing of the earlier application (Rules 4.17(iii) and 51bis.1(a)(iii)): Name: | in relation to this international application                                 |
|--------------------|--|---|
|                    | Name.  | ALTANA PHARMA AG is entitled to claim priority of earlier                     |
|                    |  | application No. 02003811.3 by virtue of the following:                        |
| VIII-3-1<br>(viii) |  | the applicant's name changed from BYK GULDEN LOMBERG CHEMISCHE FABRIK GMBH to |
| (****)             |  | ALTANA PHARMA AG on 01 July 2002  |
|                    |  | (01.07.2002)  |
| VIII-3-1           | This declaration is made for the purposes of:  | all designations  |
| (ix)               |  |   |

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| VIII-3-2 | Declaration: Entitlement to claim priority  Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application specified below, where the applicant is not the applicant who filed the earlier application or where the applicant's name has changed since the filing of the earlier application (Rules 4.17(iil) and 51bis.1(a)(iil)): | in relation to this international application   |
|----------|---|---|
|          | Name:   | ALTANA PHARMA AG  |
|          |   | is entitled to claim priority of earlier application No. 10207160.8 by virtue of the following: |
| VIII-3-2 |   | the applicant's name changed from BYK   |
| (viii)   |   | GULDEN LOMBERG CHEMISCHE FABRIK GMBH to<br>ALTANA PHARMA AG on 01 July 2002                     |
| 100.00   |   | (01.07.2002)  |
| VIII-3-2 | This declaration is made for the purposes of:   | all designations  |
| (ix)     |   |   |

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| VIII-4-1 | Declaration: Inventorship (only for                               |  |
|----------|---|--|
|          | the purposes of the designation of                                |  |
|          | the United States of America)  Declaration of inventorship (Rules | I hereby declare that I believe I am the |
|          | 4.17(iv) and 51bis.1(a)(iv)) for the                              | original, first and sole (if only one    |
|          | purposes of the designation of the                                |  |
|          | United States of America:   | inventor is listed below) or joint (if   |
|          |   | more than one inventor is listed below)  |
|          |   | inventor of the subject matter which is  |
|          |   | claimed and for which a patent is        |
|          |   | sought.                                  |
|          |   | This declaration is directed to the      |
|          |   | international application of which it    |
|          |   | forms a part (if filing declaration with |
|          |   | application).                            |
|          |   | I hereby declare that my residence,      |
|          |   | mailing address, and citizenship are as  |
|          |   | =  |
|          |   | stated next to my name.                  |
|          |   | I hereby state that I have reviewed and  |
|          | •   | understand the contents of the           |
|          |   | above-identified international           |
|          |   | application, including the claims of     |
|          |   | said application. I have identified in   |
|          |   | the request of said application, in      |
|          |   | compliance with PCT Rule 4.10, any claim |
|          |   | to foreign priority, and I have          |
|          |   | identified below, under the heading      |
|          |   | "Prior Applications," by application     |
|          |   | number, country or Member of the World   |
|          |   | Trade Organization, day, month and year  |
|          |   | of filing, any application for a patent  |
|          |   | or inventor's certificate filed in a     |
|          |   | country other than the United States of  |
|          |   | America, including any PCT international |
|          |   | application designating at least one     |
|          |   | country other than the United States of  |
|          |   |  |
|          |   | America, having a filing date before     |
|          |   | that of the application on which foreign |
|          |   | priority is claimed.                     |
| VIII-4-1 | Prior applications:   |  |



|                  |  | I hereby acknowledge the duty to         |
|------------------|--|--|
|                  |  | disclose information that is known by me |
|                  |  | to be material to patentability as       |
|                  |  | defined by 37 C.F.R. § 1.56, including   |
|                  |  | for continuation-in-part applications,   |
|                  |  | material information which became        |
|                  |  | available between the filing date of the |
|                  |  | prior application and the PCT            |
|                  |  | international filing date of the         |
|                  |  |  |
|                  |  | continuation-in-part application.        |
|                  |  | I hereby declare that all statements     |
|                  |  | made herein of my own knowledge are true |
|                  |  | and that all statements made on          |
|                  |  | information and belief are believed to   |
|                  |  | be true; and further that these          |
|                  |  | statements were made with the knowledge  |
|                  | :  | that willful false statements and the    |
|                  |  | like so made are punishable by fine or   |
|                  |  | imprisonment, or both, under Section     |
|                  |  | 1001 of Title 18 of the United States    |
|                  |  | Code and that such willful false         |
|                  |  | statements may jeopardize the validity   |
|                  |  | of the application or any patent issued  |
|                  |  | thereon.                                 |
| VIII-4-1         | Name:  | DIETRICH, Rango                          |
|                  |  | 2  |
| VIII-4-1         | Residence: (city and either US State, if applicable,                               | Konstanz, Germany                        |
| -1-2             | or country)  | ,  |
| VIII-4-1         | Mailing address:   | Im Tiergarten 16                         |
| -1-3<br>VIII-4-1 | Citizenship:   | DE                                       |
| -1-4             | Oldzonorip.  |  |
| VIII-4-1         |  | (4)                                      |
| -1-5             | (if not contained in the request, or if declaration is corrected or added under    | 1 Hay                                    |
|                  | Rule 26ter after the filing of the   | 0 3333                                   |
|                  | international application. The signature must be that of the inventor, not that of | Fab 14, 2003                             |
|                  | the agent)   | Teo (4, 210)                             |
| VIII-4-1         | Date:  |  |
| -1-6             | (of signature which is not contained in the request, or of the declaration that is |  |
|                  | corrected or added under Rule 26ter  |  |
|                  | after the filing of the International  |  |
|                  | application)   |  |



| 1             | VIII-4-1         | Name:   | EISTETTER, Klaus    |
|---------------|------------------|---|---------------------|
|               | VIII-4-1<br>-2-2 | Residence: (city and either US State, if applicable, or country)  | Konstanz, Germany   |
|               | VIII-4-1<br>-2-3 | 1 77  | Säntisblick 7       |
|               | VIII-4-1<br>-2-4 | Citizenship:  | DE .                |
|               |                  | Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filling of the international application. The signature must be that of the inventor, not that of the agent) | Tel 14, 2003        |
|               | VIII-4-1<br>-2-6 | Date: (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)   | ·                   |
| $Q_{\lambda}$ | VIII-4-1<br>-3-1 | Name:   | NEY, Hartmut        |
| 9             | VIII-4-1<br>-3-2 | Residence:<br>(city and either US State, if applicable, _<br>or country)  | Konstanz, Germany   |
|               | VIII-4-1<br>-3-3 | Mailing address:  | Peter-Thumb-Str. 46 |
|               | VIII-4-1<br>-3-4 | Citizenship:  | DE                  |
|               | VIII-4-1<br>-3-5 | Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)  | My<br>Ed. 17, 2003  |
|               | -3-6             | (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)   |                     |

| IX    | Check list   | number of sheets  | electronic file(s) attached |
|-------|--|---|-----------------------------|
| IX-1  | Request (Including declaration sheets)                     | 12  | -                           |
| IX-2  | Description  | 22  | -                           |
| IX-3  | Claims   | 2   | -                           |
| IX-4  | Abstract   | 1   | EZABST00.TXT                |
| IX-5  | Drawings   | 1   | -                           |
| 1X-7  | TOTAL  | 38  | <del></del>                 |
|       | Accompanying items   | paper document(s) attached                                | electronic file(s) attached |
| IX-8  | Fee calculation sheet                                      | /   | -                           |
| IX-13 | Priority document(s)                                       | Item(s) VI-1, VI-2  | -                           |
| IX-17 | PCT-EASY diskette  | -   | Diskette                    |
| IX-19 | Figure of the drawings which should accompany the abstract |   |                             |
| IX-20 | Language of filing of the<br>International application     | English   |                             |
| X-1   | Signature of applicant, agent or common representative     | Mil   | . 1                         |
| X-1-1 | Name   | ALTANA PHARMA AG  | (11/10/11)                  |
| X-1-2 | Name of signatory  | i. V. Dr. Herbert Ru                                      | ipp i. V. Dr. Bernd         |
| X-1-3 | Capacity   | Kratzer<br>Head of Patent Department Assistant<br>Manager |                             |
| X-2   | Signature of applicant, agent or common representative     | Rango Dilu  |                             |
| X-2-1 | Name (LAST, First)   | DIETRICH, Rango   |                             |
| Х-3   | Signature of applicant, agent or common representative     | Was ti  | ve en                       |
| X-3-1 | Name (LAST, First)   | EISTETTER, Klaus  | ,                           |
| X-4   | Signature of applicant, agent or common representative     | Contain 1   | 7                           |
|       |  | 1 " 1 / /   | •                           |

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| 10-1   | Date of actual receipt of the purported international application   |  |
|--------|---|--|
| 10-2   | Drawings:   |  |
| 10-2-1 | Received  |  |
| 10-2-2 | Not received  |  |
| 10-3   | Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application |  |
| 10-4   | Date of timely receipt of the required corrections under PCT Article 11(2)  |  |



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| 10-5 | International Searching Authority                           | ISA/EP                     |
|------|---|----------------------------|
| 10-6 | Transmittal of search copy delayed until search fee is paid |                            |
|      | EOD INT   | ERNATIONAL BUREAU USE ONLY |

Dosage forms for oral administration of a PDE 4 inhibitor whose solubility is slight are described. They contain PV as binder.